

**REMARKS**

**Status of the claims:**

With the above amendments, claims 1-6 have again been canceled and claims 7-13 have been added. Thus claims 7-13 are pending and ready for further action on the merits. No new matter has been added by way of the above amendments. Claims 7-13 have support at page 3, lines 13-17, page 2, lines 1-2, page 6, line 15-16 and in original claims 1-6. Reconsideration is respectfully requested in light of the following remarks.

**Restriction**

Claims 7-12 have been restricted by the Examiner as being part of the non-elected invention. Applicants vigorously traverse. Applicants assert that the method of using a composition should be examined with the composition as is set out in the Unity of Invention guidelines. Attached to this response, please find guidelines from the MPEP which shows that the composition and a method of using that composition should be examined together, or in other words, possesses Unity of Invention. The Examiner's attention is drawn to page AI-54, left hand column, where "(i)" appears (i.e., lines 4-8). A product (i.e., a composition) and a use of said product are considered to have Unity of Invention.

Moreover, Applicants submit an Example from the MPEP that shows that claims similar to the instantly claimed invention are shown to have Unity of Invention. The Examiner's attention is drawn to Example 3 on page AI-57 wherein "A paint containing substance X" (claim 2 - the composition claim) is said to have Unity of Invention with "a process for painting an article in which the paint contains substance X" (claim 1- the "use" or method claim). These claims correlate directly with the instantly claimed invention. Thus, Applicants submit that restriction is improper. Accordingly, it is respectfully requested that the claims be rejoined and examined together.

**Objections under 37 CFR § 1.75**

Claim 6 has been objected to for being a multiple dependent claim dependent from another multiple dependent claim. Claim 6 has been canceled. Thus, the objection is moot. Withdrawal of the objection is respectfully requested.

**Rejections under 35 USC § 112, second paragraph and 35 USC §101**

Claims 2-6 have been rejected under 35 USC §112, second paragraph and 35 USC §101 for not being a statutorily recognized class of claims in the U.S. The "use" claims of claims 2-6 have been converted into statutorily recognized "method of use"

claims in claims 7-13. Withdrawal of the rejection is respectfully requested.

Claim 1 has been rejected for the use of the transitional phrase "containing" and for citing the plural "compositions". Claim 1 has been canceled. Thus, these rejections are moot. Withdrawal of the rejections is respectfully requested.

The Examiner has rejected claims 2 and 3 for the term "and/or". Claims 2 and 3 have been canceled. Thus, these rejections are moot. Withdrawal of the rejections is respectfully requested.

The Examiner has rejected claims 2 and 4 for the use of the phrase "relative salts". Claims 2 and 4 have been canceled. Thus, these rejections are moot. Withdrawal of the rejections is respectfully requested.

**Rejections under 35 USC § 102**

Claims 1-5 are rejected under 35 USC § 102(b) as being anticipated by della Valle '566 (US Patent No. 4,399,566) and della Valle '741 (US Patent No. 4,362,741). The Examiner asserts that both della Valle '741 and della Valle '566 disclose compositions containing cloricomene.

Applicants have added a composition claim 13 wherein the preamble recites "A cholesterol level reducing pharmaceutical composition". Applicants submit that this claim falls within

the scope of the Examiner's "restriction requirement". Because it is a composition claim, Applicants herein address the differences between this claim and the cited della Valle '741 and della Valle '566 references.

First, Applicants submit that the preamble to this composition claim should be read into the claim in its entirety for the following reasons. Applicants assert that the preamble breathes "life, meaning and vitality" into the claim. Applicants submit that the element "at a dose of about 200 mg per day" in the body of the claim adds a limitation to the claim that gives the preamble of the claim "life, meaning and vitality". As such, Applicants submit that the preamble should be read into the claim.

Second, Applicants submit that neither della Valle '741 nor della Valle '566 disclose a composition that contains "about 200 mg" of cloricomene or a cloricomene salt. Accordingly, Applicants submit that neither della Valle '741 nor della Valle '566 can anticipate the instant invention because both della Valle '741 and della Valle '566 fail to disclose the elements of the instant invention. Applicants also submit that della Valle '741 and della Valle '566 can not render obvious the instant invention because neither della Valle '741 nor della Valle '566 disclose or suggest using the composition for treating a patient suffering from hypercholesterolaemia.

Regarding the method of use claims, neither della Valle '741 nor della Valle '566 disclose a method of treating a patient suffering from hypercholesterolaemia comprising administering to the patient a composition comprising cloricomene or a cloricomene salt. Accordingly, della Valle '741 and della Valle '566 cannot anticipate the instant invention because they fail to disclose the elements of the instantly claimed invention. Withdrawal of the rejection is warranted and respectfully requested.

With the above remarks and amendments, it is believed that the claims, as they now stand, define patentable subject matter such that a passage of the instant invention to allowance is warranted. A Notice to that effect is earnestly solicited.

If any questions remain regarding the above matters, please contact Applicant's representative, T. Benjamin Schroeder (Reg. No. 50,990), in the Washington metropolitan area at the phone number listed below.


Pursuant to 37 C.F.R. § 1.17 and 1.136(a), Applicants respectfully petition a one (1) month extension of time for filing a response in connection with the present application. The required fee of \$110.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees

required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By  \_\_\_\_\_

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE CLAIMS:**

Claims 1-6 have been canceled.

Claims 7-12 were added.